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DIALYZER
[Dialysator]

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PATENT CLAIMS /1*

1. Dialyzer exhibiting a tubular housing which is sealed by a poured layer on both of its ends, respectively, a multitude of semi-permeable hollow fibers which extend through the housing and the poured layer, end caps that are placed on the ends of the housing, which, respectively, exhibit a supply pipe, whereas, respectively, an intermediate space is formed between the poured layer and the end cap that, on the one hand, is connected with the supply pipes and, on the other hand, is in a fluid connection with the interior space of the hollow fibers, at least, one pipe nozzle that emerges from the housing, and a flow-directing system that is provided in the intermediate space, characterized in that the flow-directing system (40) extends diagonally across the intermediate space (38) while separating the intermediate space into a first and a second flow chamber (42, 44) and, at least, in the area of the external circumference (68) of the flow-directing system (40), a flow path (60) is provided, which connects the first and second flow chamber (42, 44) /2 with each other.

2. Dialyzer in accordance with Claim 1, characterized in that the flow-directing system is configured as a plate (46), which exhibits a multitude of raised areas (64) along its external circumference (68) while forming slots (66) or a multitude of bores (70).

3. Dialyzer in accordance with Claim 1 or 2, characterized in that the flow-directing system (40) exhibits spacer elements (58) on the bottom side (56) that faces the poured layer (22).

* Number in the margin indicates pagination in the foreign text.

4. Dialyzer in accordance with any of the Claims 1 - 4, characterized in that the flow-directing system (40) exhibits a multitude of flow-directing elements (50) on the surface facing the supply aperture (28) of the end cap (24).

5. Dialyzer in accordance with Claim 4, characterized in that the flow-directing elements (50) exhibit a shape that is radially bent outward in such a way that they impart a tangential flow component on the fluid.

6. Dialyzer in accordance with any of the Claims 1 - 5, characterized in that the inside surface of the cylindrical area of the end cap (24) exhibits an annular notch (74) in which the raised areas (64) of the plate (46) engage.

7. Dialyzer in accordance with any of the Claims 1 - 6, characterized in that the flow-directing system (40) exhibits an air relief device.

Dialyzer /3

The invention relates to a dialyzer exhibiting a tubular housing which is sealed by a poured layer on both of its ends, respectively, a multitude of semi-permeable hollow fibers which extend through the housing and the poured layer, end caps that are placed on the ends of the housing, which, respectively, exhibit a supply pipe, whereas, respectively, an intermediate space is formed between the poured layer and the end cap that, on the one hand, is connected with the supply pipes and, on the other hand, is in a fluid connection with the interior space of the hollow

fibers, at least, one pipe nozzle that emerges from the housing and a flow-directing system that is provided in the intermediate space.

This type of dialyzer is familiar to the art from US-PS 3228877 in which blood, for instance, is supplied to the hollow space of the hollow fibers via the one supply nozzle of the one end cap through the intermediate space and is subsequently discharged through the second intermediate space of the second end cap and through the discharge nozzle. If a /4
dialysis treatment is carried out, the removal of urinary substances, or water, then occurs through the pores of the semi-permeable membrane. However, on the other hand, dialysis fluid can also be supplied to the tubular housing via a supply nozzle, which flows around the outer surface of the hollow fibers and is subsequently discharged out of the pipe through an additional nozzle.

As already mentioned at the beginning of the text, the hollow fibers extend through the tubular housing and the poured layers that are located on the ends of the housing, whereas, as a rule, the hollow fibers are not channeled to the edge of the housing directly. Thus, the housing may, for instance, be expanded in the edge area, as can be deduced from US-PS 4001110, for instance, with the result that a circumferentially extending edge area in the shape of a ring is formed in the poured mass that is not permeated by the hollow fibers. Nor is this edge area connected with the end cap, which, as a rule, is slipped over the housing and subsequently connected with the housing.

Especially in the use of a hemodialyzer, this edge area leads to problems because the blood that is supplied via the supply nozzle also

flows into these edge areas and cannot drain away from them, so that a coagulation or clumping of the blood takes place. This has the result, however, that hollow fibers can become clogged during the dialysis treatment and are therefore no longer available for the dialysis treatment.

However, on the other hand, such lumps can also form in the second downstream intermediate space, which is not without problems if blood is to be transported back into the patient's body.

Therefore, attempts have been made to limit or eliminate this /5
edge area to the extent possible. Thus, end caps have been developed, for instance, which exhibit a second ring-shaped circumferentially extending wall, which comes to rest in the immediate neighborhood of the outer hollow fibers when the end cap is placed on the tubular housing, so that, essentially, the circumferentially extending area of the poured layer which is not supplied by the hollow fibers is eliminated. However, because with such an arrangement, an annular air-filled intermediate space is formed within the cap, it has to be poured with a special poured mass, which is supplied and discharged via special nozzles that are provided in the end cap.

Naturally, such a production method is very time-consuming and expensive, whereas, in addition, it cannot be absolutely guaranteed that all edge areas of the poured mass that are not permeated by the hollow fibers will be fully covered. Accordingly, even with this familiar design form, so-called dead zones can be left behind in which blood residues remain behind even after a flushing with a sterile physiological sodium

chloride solution, which is highly undesirable for the user from an optical perspective alone.

To remedy these problems, DE-OS 2646358 already suggested supplying the blood via a connecting nozzle which extends tangentially in relation to the housing or end cap instead of the supply nozzle which is arranged coaxially in relation to the longitudinal axis of the housing, which, in the dialyzer with a central dialysate intake that is described in the DE-OS, essentially eliminated the problems with the dead water zones. However, for the dialyzer mentioned in the beginning of the text, these laterally arranged nozzles can practically not be used because, again, dead zones form in the intermediate space.

In DE-OS 2646358, in an additional design form, a conical flow- /6
directing system was proposed which essentially covers the central area of the poured mass that is not permeated by the hollow fibers. However, again, on the other hand, the previously mentioned ring-shaped outer edge remains behind, so that, here again, dead zones can form.

Therefore, the invention is based on the objective of advancing a dialyzer of he kind mentioned at the beginning of the text in such a way that dead spaces formed in the edge zones of the intermediate space between the poured layer and the end cap are eliminated.

The realization of this objective occurs in that the flow-directing system extends diagonally across the intermediate space while the intermediate space is separated into a first and second flow chamber and, at least, in the area of the outer circumference of the flow-directing

system, a flow path is provided which connects the first and second flow chamber with each other.

With the inventive dialyzer, the dead spaces mentioned at the beginning of the text can be effectively eliminated because the flow-directing system conducts the incoming fluid, particularly, the blood, in such a way that the flow inevitably takes place through the outer areas.

In accordance with the invention, the blood which is introduced into the intermediate space through the supply nozzles is initially brought into contact with the flow-directing system, which then diverts the blood in an essentially radial fashion, i.e., at first, the blood is almost totally displaced into the outer area of the intermediate space.

In the outer area of the intermediate space which, usually, /7
extends around in the shape of a ring, which exhibits the dead zones through which no flow occurs that are common otherwise, flow paths in the form of perforations, holes, slots, and similar, are provided in the flow-directing system through which the blood flows from the first flow chamber into the second flow chamber. As is known to the art, the two flow chambers are usually formed in the intermediate space by the arrangement of the flow-directing system.

After flowing through this flow path which is provided in the flow-directing system, the blood flows from the outside, i.e., from the ring-shaped wall of the cap seal or the housing wall radially towards the inside and, there, it reaches the apertures of the hollow fibers through which it then continues its flow.

Thus, the fluid, particularly blood, is first directed outward in the inventive dialyzer or separator with the assistance of a flow-directing system in the intermediate space between the cap seal and the poured layer and returns from the outside towards the inside again after it has flowed through the flow-directing system with the result that the flow practically occurs around and through the entire intermediate space.

Advantageously, a plate is used as a flow-directing system that, in a first configuration, is dimensioned, so that its diameter is less than the inside diameter of the end cap. As a result, slots are formed when this plate is inserted through which the blood can flow. Moreover, advantageously, in accordance with this configuration, projections can be provided on the outer circumference as spacer elements which are dimensioned in such a way that they fixate the plate arrangement in the end cap.

Advantageously, a ring-shaped notch can circumferentially extend /8
inside the end cap in which the projections catch, so that, advantageously, the plate is fixated there, so that it cannot be lost. In accordance with such a configuration, the diameter of the plate, including the length of the projections, is frequently greater than the inside diameter of the end cap, so that the plate can only be inserted into the end cap under the impact of some force.

On the other hand, a plate is also conceivable that is loosely arranged within the end cap. In such a case, it is of advantage that, apart from the lateral spacer projections, axial spacer elements are also provided both above and below the plate level, so that a first and second flow

chamber is safely formed. Otherwise, the danger exists that one of these spaces would be compressed by the plate and would, thus, no longer be available for the passage of the flow.

Moreover, the flow-directing system may advantageously exhibit flow distributors on the surface that faces the supply nozzle, which, on the one hand, evenly distribute the inflowing fluid in radial direction and, on the other hand, can impart a specific flow direction on the supplied fluid flow. Thus, due to their shape, these flow-directing system elements can impart a tangential flow component on the inflowing fluid, whereby the impingement of the fluid on the outer wall can be mitigated. In such a case, the flow-directing system elements can, of course, also serve as spacers for the first flow chamber.

Moreover, to improve the de-aeration of the second flow chamber, i.e., of the chamber in which the fluid flows radially from the
outside to the inside, an aperture is provided in the area of the /9
center through which the de-aeration in the first flow chamber is guaranteed. Because, to the extent possible, at the beginning of the flow intake phase, the fluid or the blood is to flow uniformly from all sides, the formation of air bubbles and similar may be a concern that would remain stationary in the second flow chamber and which, thus, would block a part of the hollow fibers' apertures. This is remedied by, at least, one aperture in the central area of the flow-directing system.

Moreover, generally speaking, the shape of the plate is not critical. It may be conformed plain or with a protuberant structure, whereas the protuberant structure may benefit the flow. Thus, for instance, a plate

with a cone structure can be advantageously used for the inventive purposes.

Additional details, characteristics, and advantages of the invention will be explained by means of the following description of configuration examples with reference to the drawings. Shown are:

Figure 1, a partial section through a first configuration of an inventive dialyzer in accordance with line I-I in Fig. 2,

Figure 2, a section through the dialyzer in accordance with Fig. 1 in accordance with line II-II in Fig. 1,

Figure 3, an enlarged sectional representation through one half of the symmetrical end cap of another configuration of an inventive dialyzer in a representation which corresponds with Fig. 1.

In Fig. 1, the dialyzer (10) can be seen which is comprised of a housing (12) that expands in its end area (14) in accordance with the configuration that is shown in Fig. 1 and, again, transitions into a cylindrical end area (16). This expanded area is not of any /10
essence to the invention, however. Accordingly, the housing (12) can also be conformed as a smooth hollow cylinder.

A tubular nozzle (18) that can be connected with a hose line is provided inside the housing (12) near the end area (14). Usually, with this type of dialyzer (10), two nozzles (18) are provided which, advantageously, are arranged, so that they extend diagonally in relation to one another.

A multitude of micro-porous semi-permeable hollow fibers (20) of the type that is commonly used in a hollow fiber dialyzer are provided

in the housing (12). These hollow fibers have also been familiar to the art for a long time and are therefore not a subject of the invention.

In the housing (12), these hollow fibers are present in the form of a tightly packed bundle which may, possibly, be interwoven.

To separate the interior space of the housing (12), which represents a first chamber through which fluid flows, from the interior space of the hollow fibers (20), which represents a second chamber through which fluid, preferably blood, flows, the end area (16) of the housing (12) is equipped with a poured polymerisate layer (22) that is permeated by the hollow fibers (20), whereas the apertures of the hollow fibers (20) are not sealed off with the poured layer (22), meaning that they are open from the outside surface of the poured layer.

This type of arrangement is produced by firstly equipping the open tubular housing (12) with a bundle of hollow fibers (20), a liquid poured mass is introduced into the end area of the housing, it is allowed to cure, and, finally, the outside surfaces of the poured layer (22) /11 are worked in such a way that, on the one hand, it is plain and, on the other hand, all hollow fibers are open towards the outside.

Finally, the end cap (24), which is shown in greater detail in Fig. 3, is placed on a housing (12), which is equipped with the hollow fibers (20) in this manner, which, subsequently, is conglutinated or heat-sealed with the end area (16) of the housing (12), so that it is sterile and tight, in the usual manner.

This end cap (24) exhibits a supply nozzle (26) with a supply aperture (28), whereas the axis of the supply nozzle (26) is coaxially arranged in relation to the longitudinal axis of the housing (12).

From this supply nozzle (26), the end cap (24) extends over the cap area (30) to the outside and transitions into an end area (32) in the shape of a hollow cylinder, which, for the most part, is pushed over the end area (16) of the housing (12), as can be deduced from Fig. 3. The cap (24) is connected with this end area (32) via the heat-sealed layer (34).

When the end cap (24) is placed on the housing (12), an intermediate space (38) is formed between the surface (36) of the poured layer (22) and the inside surface of the end cap (24) that is placed on it, which is divided into a first flow chamber (42) and a second flow chamber (44) by a flow-directing system (40).

Advantageously, the flow-directing system (40) is configured as a plate (46), the diameter of which essentially corresponds with the inside diameter of the end cap (24), and which is usually designed in a circular shape. Advantageously, this plate (46) extends diagonally across the aperture of the end cap (24),which faces the poured layer (22), and essentially covers it.

As depicted in Fig. 1 or 3, the plate (46) is essentially plain. /12 On the other hand, it may also be configured in the shape of a cone, whereas, advantageously, the tip of the cone is oriented towards the supply aperture (28).

Advantageously, as can be deduced from Fig. 2, flow-directing elements (50) in the form of guide paddles are arranged on the surface (48) of the plate (46) which faces the supply aperture (28).

These flow-directing elements (50) extend in a radially curved manner, starting out in the neighborhood of the center of the plate (46) towards the outside and end in the area of the edge (52) of the plate (46). These flow-directing elements (50) may exhibit a straight or curved shape - as depicted in Fig. 2 - whereas the latter shape is preferred because it can impart a tangential flow component on the fluid.

Moreover, the flow-directing elements (50) may serve as spacers to the inside surface (54) of the end cap and, thus, prevent the plate (54) from resting against the end cap (24).

Moreover, the bottom side (56) of the plate (46), which faces the poured layer (22), also exhibits spacer elements (58) which prevent a loosely inserted plate (46) from closing off the surface (36) of the poured layer (22) and, thus, the apertures of the hollow fibers (20) when fluid flows in from the supply aperture (28). These spacer elements (58) are arranged in the shape of punctiform raised areas on the bottom side (56) of the plate (46) and can be clearly seen in Fig. 2 because the plate (46) advantageously consists of a transparent plastic material, such as polycarbonate.

To create a fluid connection between the first flow chamber and /13
the second flow chamber (44), meaning a fluid connection between the supply aperture (28) and the apertures of the hollow fibers (20) through the intermediate space (38), a flow path (60) is provided on the outer

circumference of the flow-directing system (40) which connects the two flow chambers (40 and 42) with each other. Thus, in its installed state, the plate (46) exhibits a multitude of perforations (62) on its outer circumference, which - as revealed by Figs. 2 and 3 - are formed by providing several raised areas or knobs (64) which project towards the outside in regular distribution around the outer circumference. The plate (46) with the raised areas (48) is dimensioned in such a way that it can essentially be arranged within the end cap (24) without any clearance, i.e., the raised areas (64) almost touch the inside surface of the cylindrical area of the end cap (24).

Accordingly, the flow path (60) is formed in that - as shown dashed in Fig. 2 as a section - a ring-shaped slot (66) is formed between the outer circumference of the plate (46) and the inside surface of the end area (32) of the end cap (24). The width of the slot corresponds with the height of the raised areas (64) that are distributed around the outer circumference (68) of the plate (46).

On the other hand, instead of these raised areas (64), the outer circumference (68) of the plate (46) can be directly connected with the inside surface of the end area (32) of the end cap (24). In accordance with this configuration, which is less preferred, however, bores (70) that are evenly distributed around the edge area (68) are provided in the edge area (68) of the plate (46), as is shown in dashed lines in Fig. 2. What is essential in this configuration is merely that fluid effectively flows to or through the free edge zone (72) that is formed by the end area of the housing (12) and the end area of the poured layer (22).

In accordance with an additional preferred configuration, the end cap (26) is equipped with a circumferentially extending annular notch (74) on its inside surface in the area of the intermediate space (38) to which an oblique inlet (76) connects on the inside surface of the end area (72) of the end cap (24) in the direction towards the aperture of the end cap (24) which faces the poured layer (22). This oblique inlet (76) constricts in the direction towards the annular notch (74). The insertion of the plate (46), which exhibits the raised areas (64) on the outside circumference, is thereby made easier. /14

In accordance with a preferred configuration, this plate can be inserted into the annular notch (74) with an exact fit, whereas the depth of the annular notch only amounts to a fraction of the height of the raised areas (64).

In an arrangement that is fixated in this manner, the spacer elements (50 or 58) above and below the plate (46) can, of course, be eliminated.

Moreover, the flow-directing system (40) exhibits, at least, one air relief device in the form of, at least, one bore (78) in the area of the center, which is configured in such a way that it will only let through a fraction of the incoming fluid, so that the greatly predominant part flows off via the flow path (60) which connects the first flow chamber with the second flow chamber.

The dialyzer depicted in Figs. 1 - 3 is operated in the following manner:

After the supply nozzles (26) have been connected with the blood line, blood is supplied to the supply opening (28) and subsequently comes

into contact with the flow-directing system (40), particularly, the plate (46). Advantageously, this plate (46) directs the blood to the outside by means of the flow-directing elements (50), as shown in Fig. 1 in /15 the flow direction which is indicated by the arrow. On the outer circumference (68) of the plate (46), the blood travels from the first flow chamber (42) into the second flow chamber (44) through the perforations (62) or the annularly extending slot (66) and, there, it flows radially towards the inside until it reaches the apertures of the hollow fibers (20) through which it continues its flow in the usual manner thereafter.

Thus, accordingly, the blood is radially displaced towards the outside after it has been supplied to the center and subsequently flows back radially from the outside. An air cushion may be enclosed in the second flow chamber (44) which can advantageously be displaced through the bore (78), which is provided in the plate (46).

Before and after the treatment, the dialyzer (10) is advantageously flushed with a physiological sodium chloride solution, i.e., after dialysis terminates, the blood is channeled back into the patient's body again in its entirety. With the inventive system, the dialyzer (10) can be completely purged of blood because, due to the inventive flow-directing system (40), a complete flow occurs through the dead zones that could not be cleaned in the familiar dialyzer, with the result that no blood will sediment during the dialysis and all blood residues can be removed from the dialyzer (10) after the dialysis terminates. Moreover, less rinsing solution has to be used in the inventive dialyzer (10) than in

the familiar dialyzer because the flushing is carried out with substantially greater ease.

Moreover, the inventive dialyzer has the advantage that it is essentially independent without handling and also, that it is essentially undisturbed by pump strokes due to pulsating blood pumps. To that extent, this dialyzer can also be employed at low flow rates without an /16 additional clamping of the flexible supply hoses, which is usually done in a clinical setting to increase the blood flow rate.

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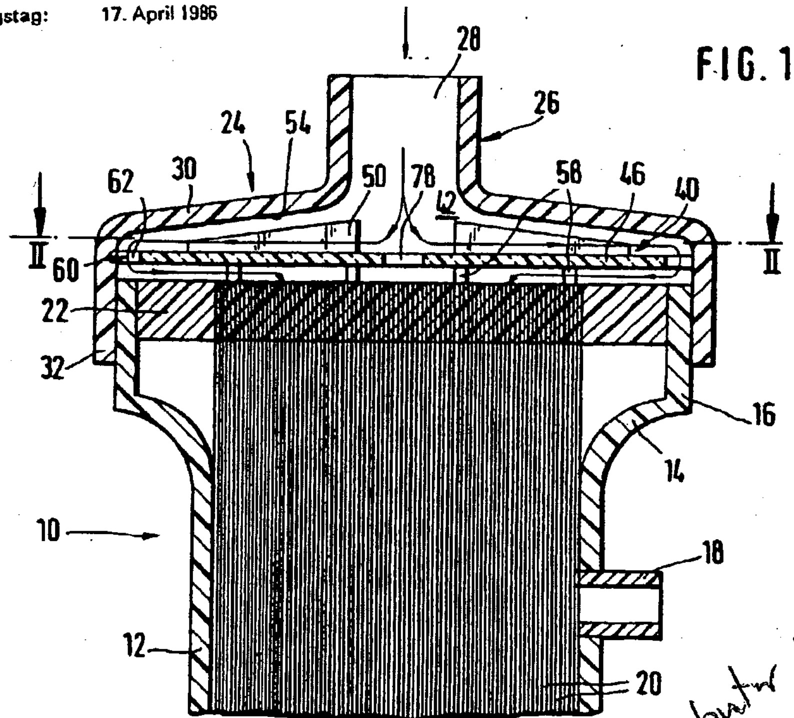
FIG. 1



Distributor is in reverse.

FIG. 2

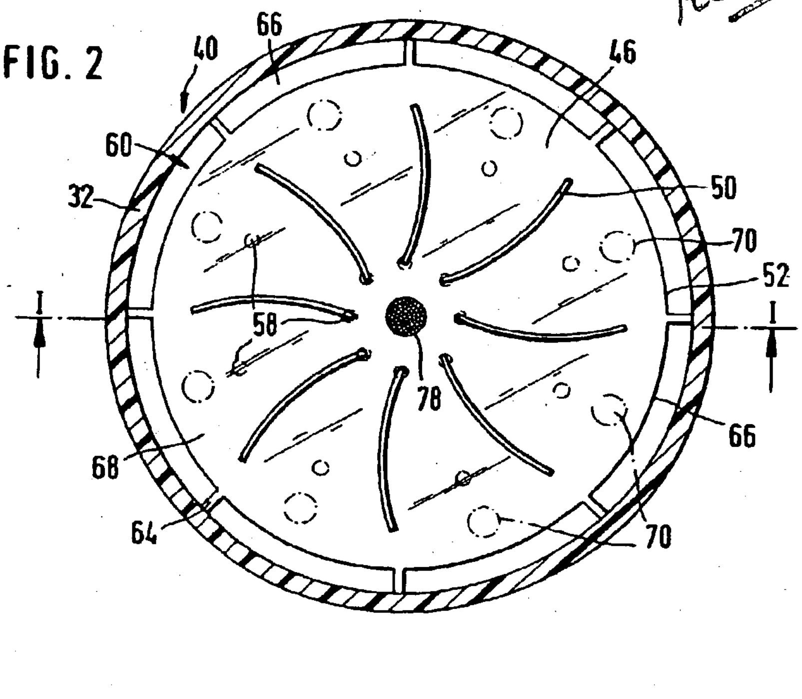
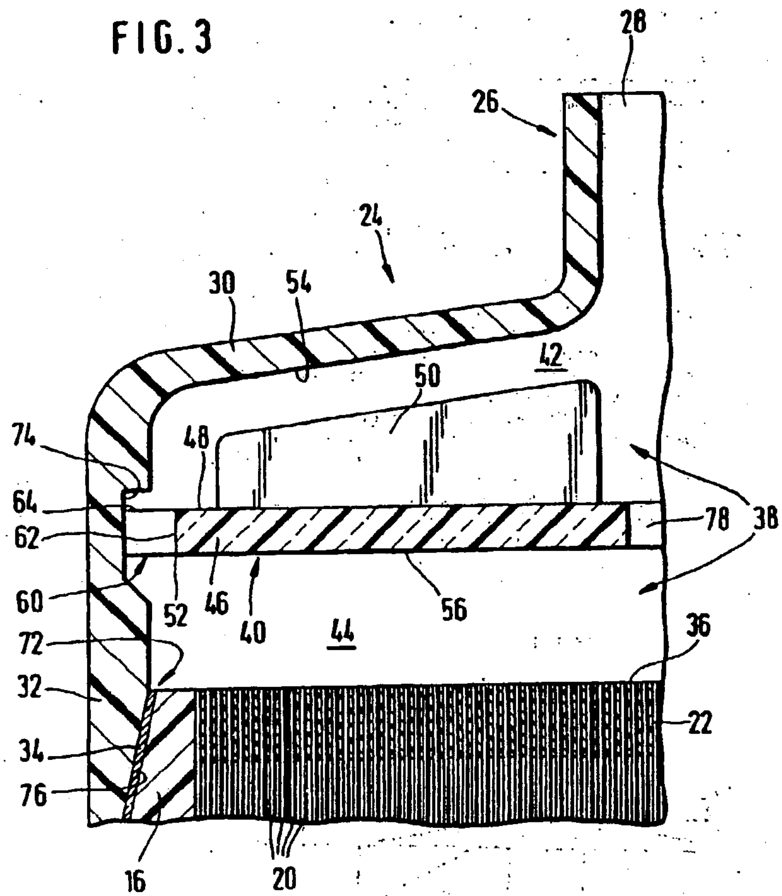


FIG. 3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